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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,471	02/12/2004	Adnan M.M. Mjalli	41305-296607	2244

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Winston-Salem, NC 27101

EXAMINER
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STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

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02/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/777,471	<b>Applicant(s)</b> MJALLI ET AL.	
	<b>Examiner</b> Laura L. Stockton	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6-32,36,37,39,63 and 65-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-32,36,37,39,63 and 65-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

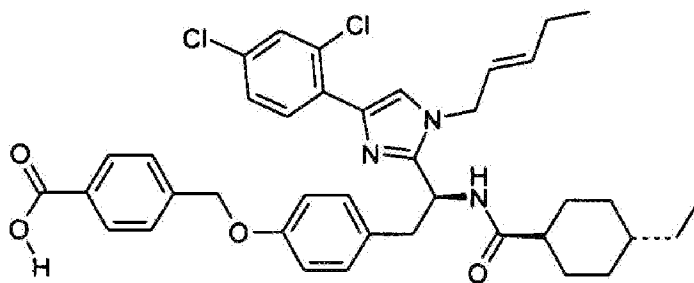
## DETAILED ACTION

Claims 1, 2, 4, 6-32, 36, 37, 39, 63 and 65-81 are pending in the application.

### *Election/Restrictions*

Applicant's election with traverse of Group III (claims 1-45), and the species of Example 146 found on pages 185-186 of the instant specification (reproduced below), in the reply filed on October 27, 2006 was acknowledged in a previous Office Action.

### Example 146



4-(4-{2-[4-(2,4-Dichloro-phenyl)-(E)-1-pent-2-enyl-1H-imidazol-2-yl]- (2S)-2-[(trans-4-ethyl-cyclohexanecarbonyl)-amino]-ethyl}-phenoxy)methyl)-benzoic acid

Art Unit: 1626

The claims within elected Group III and the IDS were examined to the extent that they are readable on the elected species of Example 146. Since no prior art was found on the elected species, the examination was expanded within elected Group III until art was found, in which case, the examination stopped and art was applied against the claims. Note, M.P.E.P. § 803.02. The subject matter of the expanded search (inclusive of the elected species of Example 146) is as follows:

**W** is  $N(R_4)$ ;

**X** is  $-C(O)-$ ;

**Ar<sub>1</sub>** is an optionally substituted phenyl;

**Ar<sub>2</sub>** is an optionally substituted phenylene; and

all other variables are as defined.

The claims that are embraced by the subject matter of the expanded search are claims 1-45. The requirement was deemed proper and therefore made FINAL in the previous Office Action.

The above indicated expanded search has not been further expanded as a result of the filing of the Amendment September 18, 2008.

Subject matter not embraced by the above indicated expanded search is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 27, 2006.

Upon reconsideration, the objection of claims 63-81 has been withdrawn. Additionally, upon reconsideration and Applicant's arguments, the rejection of claim 30 under 35 USC 112, first paragraph has also been withdrawn. Therefore, arguments pertaining to the objection and the rejection will not be addressed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 6-32, 36, 37, 39, 63 and 65-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, under the definition of R<sub>4</sub>, an "or" is needed before the last substituent listed for proper Markush language format.

In claim 1, under the definition of G, an "or" is needed before the last substituent listed for proper Markush language format.

In claim 2, under the definition of R<sub>4</sub>, an "or" is needed before the last substituent listed for proper Markush language format.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6-32, 36, 37, 39, 63 and 66-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thurieau et al. {WO 2002/10140} and Thurieau et al. {WO 99/64401}, each taken alone or in combination with each other when similar utilities are asserted.

***Determination of the scope and content of the prior art (MPEP §2141.01)***

Applicant claims imidazole compounds. **Thurieau et al. '140** (pages 2-6, 20, 21, 23-25, 39-41 and 56-58; and especially Examples 32-34 on page 155; Example 47 on page 134) and **Thurieau et al. '401** (pages 2-7, 20, 21 and 24-26, 39-41 and 56-58; and especially Example

Art Unit: 1626

33 on page 133) each teach imidazole compounds that are structurally similar to the instant claimed compounds.

***Ascertainment of the difference between the prior art and the claims  
(MPEP §2141.02)***

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

***Finding of prima facie obviousness--rational and motivation (MPEP  
§2142-2413)***

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., an anti-inflammatory).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of



obtaining additional beneficial products which would be useful in treating, for example, inflammation. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

### ***Response to Arguments***

Applicant's arguments filed September 18, 2008 have been fully considered. Applicant argues that independent claim 1, as amended by incorporating the limitations of instant claim 4 into claim 1, is not obvious over either Thurieau et al. reference since there is no overlap between the instant claimed and the genera disclosed in the Thurieau et al. references.

In response, it is disagreed that an overlap between the instant claimed invention and the Thurieau et al. references does not exist. Firstly, although the scope of instant claim 1 has been narrowed, the

Art Unit: 1626

scope of the  $R_4$  variable in instant claim 1 is not the same scope as that found in instant claim 4. For example,  $R_4$  in instant claim 1 can represent an alkyl. Secondly, the definition of "alkyl" is found on page 82, lines 10-20 of the instant specification (reproduced below).

10           As used herein, the term "alkyl" refers to a straight or branched chain  
hydrocarbon having from one to ten carbon atoms, optionally substituted with  
substituents selected from the group consisting of lower alkyl, lower alkoxy, lower  
alkylsulfanyl, lower alkylsulfenyl, lower alkylsulfonyl, oxo, hydroxy, mercapto, amino  
optionally substituted by alkyl, carboxy, carbamoyl optionally substituted by alkyl,  
15   aminosulfonyl optionally substituted by alkyl, silyloxy optionally substituted by alkoxy,  
alkyl, or aryl, silyl optionally substituted by alkoxy, alkyl, or aryl, nitro, cyano, halogen, or  
lower perfluoroalkyl, multiple degrees of substitution being allowed. Such an "alkyl"  
group may containing one or more O, S, S(O), or S(O)<sub>2</sub> atoms. Examples of "alkyl" as  
used herein include, but are not limited to, methyl, n-butyl, t-butyl, n-pentyl, isobutyl, and  
20   isopropyl, and the like.

Note, per Applicant's definition, "alkyl" embraces an unsubstituted alkyl or substituted with substituents such as oxo or lower alkoxy. See in Thurieau et al.

'140, for example, Compound 47 on page 134 and Compound 32 on page 155. The table below shows how the instant

Art Unit: 1626

claimed compounds are taught in, for example, Thurieau et al. '140.

Applicant's compound	Thurieau et al. '140
<b>W</b> is -N(R <sub>4</sub> )- wherein <b>R</b> <sub>4</sub> is alkyl	<b>R</b> <sup>1</sup> is -(CH <sub>2</sub> ) <sub>m</sub> -Z <sup>1</sup> wherein <b>m</b> is zero and <b>Z</b> <sup>1</sup> is an optionally substituted (C <sub>1</sub> -C <sub>12</sub> ) alkyl
<b>a</b> is one; <b>b</b> is one; <b>Ar</b> <sub>2</sub> is phenyl; <b>L</b> <sub>1</sub> is -O-; and <b>T</b> is alkyl	<b>R</b> <sup>3</sup> is -(CH <sub>2</sub> ) <sub>m</sub> -E-(CH <sub>2</sub> ) <sub>m</sub> -Z <sup>2</sup> Wherein <b>m</b> is 1, <b>E</b> is a bond, <b>m</b> is zero and <b>Z</b> <sup>2</sup> is an optionally substituted phenyl See page 5, lines 21-27 wherein an alkoxy group is listed as a substituent
<b>A</b> is hydrogen	----- bond is absent
<b>R</b> <sub>3</sub> is hydrogen <b>X</b> is -C(O)-; and <b>R</b> <sub>2</sub> is -J-alkyl wherein J is -O-	<b>R</b> <sup>2</sup> is hydrogen; <b>R</b> <sup>4</sup> is -C(=Y)-X <sup>2</sup> wherein <b>Y</b> is O; and <b>X</b> <sup>2</sup> is -(CH <sub>2</sub> ) <sub>m</sub> -Y'-X <sup>3</sup> wherein <b>m</b> is zero, <b>Y'</b> is O and <b>X</b> <sup>3</sup> is an optionally substituted (C <sub>1</sub> -C <sub>12</sub> ) alkyl
<b>Ar</b> <sub>1</sub> is phenyl <b>R</b> <sub>1</sub> is hydrogen	<b>R</b> <sup>5</sup> is an optionally substituted aryl(i.e. phenyl) <b>R</b> <sup>6</sup> is hydrogen

Therefore, there is an overlap between the instant claimed compounds and the compounds of each of the Thurieau et al. references. The rejection is deemed proper and therefore, the rejection is maintained.

***Allowable Subject Matter***

The elected species of Example 146, found on pages 185-186 of the instant specification, is allowable over the art of record.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains subject matter drawn to inventions nonelected (see above indicated expanded search) with traverse in the reply filed on October 27, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the

Art Unit: 1626

examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton/  
Laura L. Stockton  
Primary Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600

February 9, 2009